

Effectiveness of yoga program in the management of diabetes using community health workers in the urban slums of Bangalore city: A non-randomized controlled trial

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ABSTRACT

Trial Design: Nonrandomized controlled trial. **Methods:** Nonrandomized controlled trial. This was an interventional study that was conducted in 4 slums of Bengaluru. Of the 256 diabetes participants, only 109 people agreed to participate in the program. Of 109 people, 52 people agreed to participate in the intervention (agreed to learn and practice Yoga) while the remaining 57 people were assigned to nonintervention group. Randomization and blinding could not be done. **Objective and Outcome:** The study was conducted with objective of assessing the effectiveness of Yoga, Pranayama, and Sudarshan Kriya in the community-based management of diabetes mellitus. The primary outcome variable was Hb1Ac and secondary outcome variables were systolic blood pressure (SBP), diastolic blood pressure (DBP), adherence to medication, and changes in lifestyle. **Results:** The study was conducted for 40 days. Community health workers made a total of 6 visits during the study. All the 109 participants were available for weekly follow-up. There were no drop outs among the study population. Statistically significant change was seen in the consumption of vegetable ($\chi^2 = 15.326$, $P < 0.005$), fruits ($\chi^2 = 16.207$, $P < 0.005$), salty food ($\chi^2 = 14.823$, $P < 0.005$), bakery food ($\chi^2 = 10.429$, $P < 0.005$) and fried food ($\chi^2 = 15.470$, $P < 0.005$), adherence to metformin ($\chi^2 = 41.780$, $P < 0.005$) and other medication ($\chi^2 = 21.871$, $P < 0.005$) and proportion of patients with DBP under control ($\chi^2 = 9.396$, $P < 0.005$) and proportion of people with glucose random blood sugar under control ($\chi^2 = 29.693$, $P < 0.005$) between the two groups following the intervention. Statistically significant change was also seen in the proportion of people with SBP/DBP $\leq 140/90$ ($\chi^2 = 10.635$, $P < 0.005$) between the two groups. **Conclusion:** The Yoga program was successful in improving dietary practices and medication adherence and in increasing the proportion of diabetics and hypertensive patients under control.

Keywords: Community health workers, diabetes, Yoga

Introduction

Diabetes has emerged as a major health care problem in India. According to the Diabetes Atlas published by the International Diabetes Federation, there are an estimated 40 million persons with diabetes in India in 2007 and this number is predicted to rise to almost 70 million people by 2025 by which time every fifth diabetic subject in the world would be an Indian.^[1,2] Generalized

obesity, central obesity, sedentary lifestyle, and consumption of junk food have been reported to be associated with increased prevalence of diabetes and impaired glucose tolerance in many studies, and lifestyle modification is recommended to reduce the prevalence and to control the blood sugar.^[3-5] At present, the challenges for diabetes care in India and in other Asian countries include improved education to alert the population about the risk factors for diabetes, training of patients to manage their disease more effectively, and development of more structured care delivery.^[6]

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The use of community health workers [CHWs] in the management of diabetes has been studied in many countries and their use has resulted in improved blood sugar control, adherence to dietary changes, and physical activity.^[2,7-9] The use of CHWs is increasingly being viewed as a cost-effective approach to improving community health and well-being, reducing health disparities, and bridging the cultural and social barriers between underserved communities and the health-care system.^[7,10] Various exercise regimes such as aerobic exercise and walking have also been studied for the control of diabetes.^[11] Yoga and Pranayama which is an ancient science and part of rich Heritage of Indian culture is being applied in the field of therapeutics in the modern time.^[12] Unlike any other exercise, Yoga and Pranayama have a positive impact on mental, physical, and spiritual dimension of the individuals. There have been some studies in the recent past to assess its use in diabetes control.^[13,12]

Methods

Written informed consent was taken from the participants in the local language, and the study was approved by the Ethics Committee of the Art of Living Foundation.

Trial design

Nonrandomized controlled trial.

Participants

This was an interventional study that was conducted in 4 slums of Bengaluru - Ashwath Nagar, Nagamma Nagar, Vimmy Colony and Mariyappana playa with a total population of 6127. A baseline survey was conducted before the study. All the people above 35 years of age (2013) were screened for diabetes. They were also assessed for risk factors such as age, sex, family history, dietary habits, addictions, lifestyle, body mass index, and central obesity. The prevalence of diabetes in the target population was found to be 12.33%. The details of the study are given elsewhere.^[14] Of the 256 diabetes participants, only 109 people agreed to participate in the program. Of 109 people, 52 people agreed to participate in the intervention (agreed to learn and practice Yoga) while the remaining 57 people were assigned to nonintervention group.

Intervention and implementation

Four local women (CHWs) were recruited from the same local area with same cultural background to implement

the project. They underwent 81 h of training program to implement the project. Fifty-six hour of training was done on leadership qualities and other soft skills by the art of living organization and 10 h of training on the basics of diabetes and hypertension and another 15 h of training on measuring blood sugar using glucometer (FreeStyle Optium). Blood pressure (BP) using Omron digital machine, and weight measurement. They were trained on imparting health education using flip charts. After the baseline survey, 4 months were taken to recruit the participants into the two groups, to organize baseline HbA1c test and to teach Yoga, Pranayama, and Sudarshan Kriya.

Components of the intervention

Home visit by community health worker

CHW visited both the intervention group and nonintervention group once a week. They filled up the follow-up information sheet which included data on glucose random blood sugar (GRBS), BP, weight, physical activity, dietary practices, adherence to medications by pill count, smoking, and alcohol consumption. CHWs made a total of 6 visits during the study.

Monthly clinic

Both intervention group and nonintervention group attended monthly clinic. GRBS and BP were measured, and drugs were prescribed by the project doctor. Some of the participants visited Government Hospital, ESI Hospital, and Private Clinics.

Daily practice of Yoga

Intervention group attended Yoga sessions daily for a total duration of 40 min. These sessions included asanas such as Shalabasan, Bhujangasana, Vipareetshalabasan, Dhanurasana, Naukasana Pawanamuktasana, Natarajasan, Ardhamatsyendrasana, Parvathasan, Yogamudra, Nadishodana Pranayama, Bhastrika Pranayama, and Sudarshan Kriya. These sessions were conducted by a Yoga teacher from the Art of Living Foundation. Each session ended with discussion on practices and experience sharing. The sessions were practiced daily for 40 days.

Objective

This study was conducted with the objective of assessing the effectiveness of Yoga, Pranayama, and Sudarshan Kriya in the community-based management of diabetes mellitus.

HbA1c levels were measured at the beginning and end of 40 days intervention

Strategies	Intervention group (CHW intervention and practice of Yoga)	Nonintervention (CHW intervention and no Yoga practice)
Diet awareness and adherence	✓	✓
Sensitization on adverse impact of smoking and alcohol consumption	✓	✓
Awareness about diabetics - flipchart usage	✓	✓
Weekly follow-up by CHW at home	✓	✓
Monthly clinics participation	✓	✓
Practice of Yoga, Pranayama, and Sudarshan Kriya	Attendance was compulsory	Not informed
Checkup at home (GRBS and BP)	✓	✓

CHW: Community health workers; BP: Blood pressure; GRBS: Glucose random blood sugar

Outcome

The primary outcome variable was Hb1Ac and secondary outcome variables were SBP, DBP, adherence to medication, and changes in lifestyle.

Sample size

We estimated the sample size based on the results of a study on the effectiveness of Yoga in noninsulin-dependent diabetic patients by Sahay,^[12] who reported the standard deviation (SD) HbA1c before intervention to be 3.82 and a SD HbA1c after intervention to be 3.34 along with a difference of 1.49 between the two mean values of HbA1c before and after the intervention. Using the above values and a confidence level of 95%, we estimated that the minimum sample size required for our study would be 45 diabetic patients in each group (Total of 90 diabetics). However, we included all the 109 diabetics in the study area who consented to participate in the study.

Randomization

This was a nonrandomized controlled trial. Of 109 people, 52 people agreed to participate in the intervention (agreed to learn and practice Yoga) while the remaining 57 people were assigned to nonintervention group. Blinding could not be done in this study.

Statistical methods

Data were entered into Microsoft Excel and analyzed using the standard statistical software. Intension to treat analysis was done. We compared characteristics between the intervention and control groups at baseline and the end of the intervention using Pearson's Chi-square test and Fisher's exact probability test as applicable. The mean of the outcome measure (HbA1c, systolic, and diastolic BP [SBP and DBP]) values before and after intervention we compared using paired *t*-test. The value of $P < 0.05$ was considered statistically significant for all statistical analyses.

Results

Participants flow and recruitment

After the baseline survey of the population, 4 months were taken to recruit the participants for the study. The study was conducted for 40 days. CHWs made a total of 6 visits during the study. All the 109 participants were available for weekly follow-up. There were no dropouts among the study population. However, 17 patients (5 from intervention and 12 from nonintervention) did not get the HbA1c test postintervention because of their nonavailability on that particular day.

Table 1 describes the adherence to the Yoga program. A total of 40 (95.25%) subjects attended all the days, 3 were irregular, and 9 did not attend the program.

Baseline data

Table 2 describes the baseline sociodemographic variables and risk factor profile. The mean age of the group was 52.94 years. Of a total of 109 study participants, 72.47% were females and

Table 1: Adherence to the Yoga program

Adherence to the Yoga program (days/week)	Number of subjects (%)
Did not attend even once in a week	9 (14.5)
1-3	1 (50)
4-6	2 (66.7)
7	40 (95.2)
Total	52 (47.7)

27.52% were male. Regarding dietary habits of participants, 2% of them consumed vegetables daily, 0.9% consumed fruits daily, 15.59% of them consumed salty food less than a week, 19.26% consumed bakery item less than a week, 9.17% consumed fried food less than a week, and 10.09% consumed red meat less than a week. Only 3.66% were adherent to medication. SBP was <140 in 39.44% of them and 68.80% had DBP <90 . HbA1c was <7.5 in 29.35% and 24.77% had GRBS <180 . The difference in variables between intervention and nonintervention group was not statistically significant.

Outcomes

Table 3 shows the comparison of changes among the groups. Statistically significant change was seen in the consumption of vegetable ($\chi^2 = 15.326$, $P < 0.005$), fruits ($\chi^2 = 16.207$, $P < 0.005$), salty food ($\chi^2 = 14.823$, $P < 0.005$), bakery food ($\chi^2 = 10.429$, $P < 0.005$) and fried food ($\chi^2 = 15.470$, $P < 0.005$), adherence to metformin ($\chi^2 = 41.780$, $P < 0.005$) and other medication ($\chi^2 = 21.871$, $P < 0.005$) and proportion of patients with DBP under control ($\chi^2 = 9.396$, $P < 0.005$), and proportion of people with GRBS under control ($\chi^2 = 29.693$, $P < 0.005$) between the two groups following the intervention. Statistically significant change was also seen in the proportion of people with SBP/DBP $\leq 140/90$ ($\chi^2 = 10.635$, $P < 0.005$) between the two groups. However, we did not find any difference in the proportion of people with HbA1c under control between the two groups. In addition, the mean SBP did not differ between the two groups following the intervention.

Table 4 describes mean and SD of the outcome before and after intervention in the intervention group and nonintervention group. Statistically significant difference was found for HbA1c, SBP, and DBP in the intervention group. Mean SBP decreased by 14 mmHg and DBP by 9 mmHg in the intervention group. In the nonintervention group, systolic decreased by 5.95 mmHg and diastolic by 2.65 mmHg. Mean HbA1c decreased from 8.9% to 7.5% in the intervention group and from 8.4% to 7.8% in the nonintervention group. Hence, the change is 1.4% in the intervention group and 0.6% in the nonintervention group.

Harm

No side effect was reported during the study period.

Discussion

In this study, use of the daily practice of Yoga, Pranayama, and Sudarshan Kriya was assessed for improvement in the adherence

Table 2: Baseline sociodemographic variables and risk factor profile

Variables	Intervention group (n=52) (%)	Nonintervention group (n=57) (%)	Total (n=109)	P
Age				
<60	40 (46.51)	46 (53.48)	86	0.692
>60	12 (52.17)	11 (47.82)	23	
Sex				
Female	38 (48.1)	41 (51.9)	79	0.893
Male	14 (46.7)	16 (53.3)	30	
Diet				
Vegetable: 7 days a week	0	3 (100)	3	0.245*
Fruits: 7 days a week	0	1 (100)	1	1*
Salty food: Less than once a week	8 (47.1)	9 (52.9)	17	0.954
Bakery items: Less than once a week	9 (42.9)	12 (57.1)	21	0.620
Fried food: Less than once a week	5 (50)	5 (50)	10	1*
Red meat: Less than once a week	4 (36.4)	7 (63.6)	11	0.427
Adherence to medication				
Metformin (took all doses)	18 (60)	12 (40)	30	0.321
Other medication (took all doses)	27 (62.79)	16 (37.20)	43	0.077
BP				
Systolic ≤ 140	20 (46)	23 (54)	43	0.840
Diastolic ≤ 90	33 (44)	42 (56)	75	0.250
Systolic ≤ 140 /diastolic ≤ 90	20 (46)	23 (54)	43	0.840
GRBS				
<180	11 (44)	14 (56)	25	0.673
HbA1c				
<7.5	8 (50)	8 (50)	16	0.690

*Fisher's exact test. BP: Blood pressure; GRBS: Glucose random blood sugar

Table 3: Comparison of changes among the groups postintervention

Variables	Intervention group (n=52) (%)	Nonintervention group (n=57) (%)	Total (n=109)	P
Diet				
Vegetable: 7 days a week	27 (61.4)	17 (38.6)	44	0.023
Fruits: 7 days a week	3 (75)	1 (25)	4	0.001
Salty food: Less than once a week	47 (58.8)	33 (41.3)	80	0.000
Bakery items: Less than once a week	50 (54.3)	42 (45.7)	92	0.001
Fried food: Less than once a week	44 (61.1)	28 (38.9)	72	0.000
Red meat: Less than once a week	28 (57.1)	21 (42.9)	49	0.075
Adherence to medication				
Metformin (took all doses)	51 (68.91)	23 (31.08)	74	0.000
Other medication (took all doses)	52 (53.60)	45 (46.39)	97	0.000
BP				
Systolic ≤ 140	38 (55)	32 (45)	70	0.065
Diastolic ≤ 90	49 (54)	41 (45)	90	0.002
Systolic ≤ 140 /diastolic ≤ 90	38 (61)	24 (39)	62	0.001
GRBS				
<180	39 (75)	13 (25)	52	0.000
HbA1c				
<7.5	22 (57.89)	16 (42.10)	38	0.273

BP: Blood pressure; GRBS: Glucose random blood sugar

to diet changes, medications, control of hypertension, and control of diabetes.

This study was successful in improving the adherence to dietary changes in the intervention group compared to the nonintervention group except for the red meat in a statistically significant manner. There is no similar study in the past to compare the results. However, one study showed

a significant difference in the mindful eating score relative to yoga tenure and also vegetable and fruits intake relative to Yoga tenure.^[15] Since Yoga can help to unite the mind and body, it can be useful in regulating appetite, decreasing food preoccupation, enhancing body awareness, and boosting body satisfaction. The longer one participates in Yoga, the more self-awareness and positive impact on body image/eating they develop. Yoga can help eliminate binge-eating patterns. This

Table 4: Paired t-test of intervention group and nonintervention group

	Intervention group (mean±SD)		P	Nonintervention group (mean±SD)		P
	Preintervention	Postintervention		Preintervention	Postintervention	
HbA1c	8.900±2.0368	7.772±1.2693	0.001	8.43±1.4582	7.925±1.4811	0.053
SBP	148.67±18.274	134.90±13.689	0.000	148.26±24.722	142.32±19.6	0.062
DBP	88.69±11.690	79.77±9.432	0.000	85.16±10.683	82.51±10.497	0.113
GRBS	263.88±98.542	158.29±51.581	0.000	245.54±92.55	210.54±74.74	0.710

BP: Blood pressure; SD: Standard deviation; SBP: Systolic blood pressure; DBP: Diastolic blood pressure; GRBS: Glucose random blood sugar

may be due to the meditation aspect and ability to heighten mindfulness.^[16]

The study showed statistically significant improvement in the adherence to medications. There is no such study in the past to compare the results.

In this study, mean SBP decreased by 14 mmHg and DBP by 9 mmHg in the intervention group which was statistically significant. In the nonintervention group, systolic decreased by 5.95 mmHg and diastolic by 2.65 mmHg. A study done by Wolff *et al.* also showed an improvement in DBP for the Yoga at home group which was significantly greater than that for the control group (-4.4 ± 1.6 mmHg vs. 0.8 ± 1.6 mmHg; OC, $P < 0.05$) and no change in the SBP.^[17] A systematic review of 17 studies (22 trials) demonstrated Yoga to be associated with a small but significant decline in both SBP and DBP (-4.17 and -3.26 mmHg, respectively).^[18]

In our study, mean HbA1c decreased from $8.900 \pm 2.0368\%$ to $7.772 \pm 1.2693\%$ in the intervention group. The change in the HbA1c was statistically significant. In a study conducted by Malhotra *et al.*, after 40 days of practice of Yoga paired reading of before and after Yoga asanas was taken and analyzed among 20 patients. HbA1c decreased from $10.25 \pm 0.5\%$ to $8.68 \pm 0.4\%$ ($P = 0.004$).^[13] Another study conducted by Sahay also showed similar results wherein 28 Type 2 diabetics and 4 Type 1 diabetics were studied for 1 month. They practiced 4 types of Pranayama for 30 min followed by Shavasana for 15 min. Patients developed a sense of well-being within 7–10 days and showed a significant fall in fasting and postprandial blood glucose values. Fasting sugar decreased from 148.19 ± 43.13 to 108.19 ± 21.05 and postprandial from 278.50 ± 43.13 to 188.50 ± 79.37 .^[12]

In our study, we did not find a statistically significant difference in the mean HbA1c value between the intervention and the nonintervention groups. This is probably due to the short duration of intervention. This reflects on the need for more studies to look at evidence on the usefulness of Yoga in the control of diabetes and hypertension.

Evidence of mechanism of action of Yoga

Leptin has been shown to play a proinflammatory role while adiponectin has anti-inflammatory properties. Leptin was found to be significantly higher among novices compared to regular

practitioners of Yoga. The frequency of Yoga practice had significant inverse relationship with leptin while adiponectin levels were higher among practitioners of Yoga. This raised the possibility that long-term/more intensive Yoga practice could have beneficial health consequences by altering leptin and adiponectin.^[19]

Sudarshan Kriya Yoga and Pranayam program have been found to have a rapid and significantly greater effect on gene expression in peripheral blood mononuclear cells which results in rapid gene expression alterations, which may be the basis for their longer-term health effects.^[20]

Practice implication

One of the major challenges in the management of diabetes is adherence to self-care behavior. Some of the Indian studies have revealed very poor adherence to self-care behavior, adherence to diet has been as low as 29% and adherence to exercise 19.5% and adherence to medication 70%.^[21] Although multiple demographic, socioeconomic, and social support factors can be considered as positive contributors in facilitating self-care activities in diabetic patients, role of Yoga in promoting adherence to self-care behavior is crucial. A primary care physician can play a vital role in promotion and facilitation of self-care behavior of diabetes patients by encouraging them to practice Yoga.

India is the home of Yoga. The benefits of Yoga is not only limited to diabetes but has a positive impact on all noncommunicable diseases. Yoga has been shown to be effective in bring down BP, cholesterol, and ischemic heart disease.^[22,23] Hence, the inclusion of Yoga in the primary care delivery system can be a vital step in combating the challenge of rising NCDs in India.

The aim of our study was to assess the effectiveness of Yoga program in the management of diabetes as multidisciplinary approach in the primary health-care delivery system. Through this evidence, we hope to promote and advocate Yoga in the management of diabetes at the primary care level.

Limitation of the study

In this study, randomization could not be done; participants interested in practicing Yoga were included in the intervention group. HbA1c, which is the main outcome measure, was assessed after only 40 days of intervention. This duration of intervention and interval is too short to reflect a change in HbA1c.

Conclusion

The Yoga program was successful in improving dietary practices and medication adherence and in increasing the proportion of diabetics and hypertensive patients under control. However, more studies of longer duration are needed to show its effectiveness in short- and long-term control of diabetes and hypertension.

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Conflicts of interest

There are no conflicts of interest.

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